UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/464,416	12/16/99	THANAVALA	Y	RPP:156BUS

HM22/0221

DUNN & ASSOCIATES
P O BOX 96
NEWFANE NY 14108

EXAMINER	
FLOOD,M	
ART UNIT	**PAPER NUMBER**
1651	13
DATE MAILED:	02/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.	Applicant(s)
09/464,416	Thanavala et al.
Examiner	**Group Art Unit**
Michele Flood	1651

THE PERIOD FOR RESPONSE: [check only a) or b)]

a) ☒ expires 3 months from the mailing date of the final rejection.

b) ☐ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due two months from the date of the Notice of Appeal filed on _____ (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on *Feb 1, 2001* **has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:**

☒ The proposed amendment(s):

- ☐ will be entered upon filing of a Notice of Appeal and an Appeal Brief.
- ☒ will not be entered because:
  - ☒ they raise new issues that would require further consideration and/or search. (See note below).
  - ☐ they raise the issue of new matter. (See note below).
  - ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
  - ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: *Applicant has inserted a new limitation in independent Claim 1 which would require further consideration and/or search.*

☐ Applicant's response has overcome the following rejection(s):

☐ Newly proposed or amended claims _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.

☒ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See attached paper.

☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: _____

Claims objected to: _____

Claims rejected: *1, 3, 5, and 7-10*

☐ The proposed drawing correction filed on _____ ☐ has ☐ has not been approved by the Examiner.

☐ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ .

☐ Other

DETAILED ACTION

Acknowledgment is made of the receipt of Applicant's response made under 37 CFR 1.111 and 1.113.

Full consideration has been given to Applicant's arguments and declaration, however, Applicant's arguments do not distinguish over the prior art of record. Applicant argues that the enablement rejection made under 35 U.S.C. 112, first paragraph, is a new ground of rejection and that the final rejection necessitated by amendment made by the examiner is improper. Applicant further argues that the final rejection based upon non-enablement should have been made in the original rejection because the amendment of the claims did not make the previous office action rejection necessary. However, this is not found persuasive because the **substantial amendment of the claims**, which was made by Applicant necessitated the adjustment in the rejection. The original presentation of the claims did not incorporate the limitations of amended Claim 3, which incorporate each of the non-enteric pathogens antigens selected from the group consisting of the infectious diseases of hepatitis C, hepatitis delta, yellow fever, dengue, hemorrhagic fever, tetanus, *Staphylococcus aureus*, yaws, relapsing fever, rat bite fever, bubonic plague and spotted fever. In the originally presented claims, only Hepatitis B antigen was referred to in the claims, which narrowed the limitation of Claim 1 for the antigen to a non-enteric pathogen. Therefore, the rejection made under 35 U.S.C. was **indeed** a result of the substantial amendment to the claims made by Applicant. Hence, the rejection made in the previous office action is maintained for the reasons given in the previous office action and repeated here below.

The specification broadly discloses non-enteric pathogens that invade the epidermis of mammals via punctures, abrasions, cuts or other breaches in the skin, e.g. blood transfusions which can be used as sources of NEPA to raise a protective enteric immune response in mammals. However, the specification does not provide sufficient guidance as to how one of ordinary skill in the art would provide an immune response in a mammal and/or a human to a NEPA other than the non-enteric pathogen antigen, hepatitis B surface antigen. The specification does not disclose other specific non-enteric pathogen antigens which have been subjected to the claim-designated therapeutic regimen, nor does the specification teach any methodology associated with the making of genetically altered plant materials expressing any other NEPA other than the non-enteric pathogen antigen, hepatitis B surface antigen. In regard to Claim 3, the specification other than the mere suggestion on page 1, lines 13-16 does not provide guidance as to how to use the instantly claimed invention to provide an immune response to any all diseases caused by a non-enteric pathogen that invade the epidermis of mammals via punctures, abrasions, cuts or other breaches in the skin. Moreover, there is inadequate guidance as to how one of ordinary skill in the art would use the instantly claimed invention to genetically altered plant material to express any and all non-enteric pathogens other than HBsAg.

Inventions targeted for human therapy bear a heavy responsibility to provide supporting evidence because of the unpredictability in biological responses to therapeutic treatment. The standard of enablement is higher for such inventions because effective treatments for providing immunological responses to the instantly disclosed pathogens are relatively rare, and may be

unbelievable in the absence of supporting evidence. Claims drawn to compositions intended for the administration of compounds to humans generally require supporting evidence which clearly Claims drawn to compositions intended for the administration of compounds to humans generally require supporting evidence which clearly define the ingredients or constituents contained therein because of the unpredictability in biological responses to therapeutic treatments. In order to enable the skilled artisan to practice the invention as claimed, applicant would have to demonstrate the functional effect and describe the effective amounts of each ingredient for the administration of the composition intended for a therapeutic treatment. Accordingly, it would take undue experimentation without a reasonable expectation of success to determine which amounts of the instantly claimed plant materials expressing a non-enteric pathogen selected from those pathogens which cause the diseases hepatitis C, hepatitis delta, yellow fever, dengue, hemorrhagic fever, tetanus, *Staphylococcus aureus*, yaws, relapsing fever, rat bite fever, bubonic plague and spotted fever, and other ingredients, i.e. adjuvant, therein which would have the claimed functional effect for providing a an immune response in a mammal, wherein the specific immune response to the NEPA was stronger than a response specific to NEPA caused by the NEPA alone.

LEON B. LANKFORD, JR.
PRIMARY EXAMINER

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Michael Wityshyn whose telephone number is (703) 308-4743.

mcf

February 12, 2001